Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte EILEEN MCFARLAND

Appeal No. 2003-1217
Application No. 09/724,135

ON BRIEF

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-13, all of the claims in the application. The independent claims (claims 1, 6, 10, and 11) read as follows:

1. A method for aiding in a diagnosis of a predisposition to psychosis in a progeny who possesses Cw blood antigen, comprising:

(a) obtaining a biological sample from the progeny's mother; and

(b) determining presence of anti Cw antibody in the biological sample, wherein the presence of an anti Cw antibody in the biological sample is indicative of a histocompatibility and a predisposition of the progeny to psychosis.

6. A method of screening for predisposition to psychosis, comprising:

(a) obtaining a sample from a maternal donor; and

(b) determining presence of an anti-Cw antibody in the sample, wherein the presence of an anti-Cw antibody is indicative of a predisposition to psychosis if donor's progeny possess Cw antigen.

10. A kit for use in diagnosis of psychosis, comprising a sample containing anti-Cw, a detector that binds to anti-Cw antibody, and instructions for using the antibody and detector to diagnose a predisposition to psychosis.

11. A method for diagnosing or aiding in a diagnosis of a predisposition to a psychotic disorder, comprising determining presence of anti-Cw antibody in a sample from an individual with Cw antigen, wherein the presence of anti-Cw antibody indicates a positive diagnosis.

The examiner relies on the following references:[1]

Curtin et al. (Curtin), "Mild hemolytic disease of the newborn due to anti-C^w," Amer. J. Med. Technol., Vol. 33, No. 3, pp. 175-178 (1967)

Bowman et al. (Bowman), "Maternal C^w alloimmunization," Vox Sang., Vol. 64, pp. 226-230 (1993)

Mouro et al., (Mouro), "Molecular basis of the RhC^w (Rh8) and RhC^x (Rh9) blood group specificities," Blood, Vol. 86, No. 3, pp. 1196-1201 (1995)

Claims 1-13 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

We reverse and enter new grounds of rejection under 37 CFR § 1.196(b).

[1] Despite the examiner's statement that "[n]o prior art is relied upon," Examiner's Answer, page 3, the references cited above are cited as support for the statement that "numerous studies . . . disclose the measurement of these antibodies for the determination of hemolytic disease." Id.

Background

Blood antigens include the Rhesus (Rh) factors C, D, E, c, and e. See the specification, page 5. Cw is an Rh antigen "that is present in about 2% of the general Caucasian population." Id.

Rh incompatibility is a condition that can arise when a mother "produce[s] antibodies directed to a factor her progeny possesses due to a transfer of antigen-positive fetal blood." Id. "[T]hese antibodies then may cross the placenta and attack the fetal blood cells because her immune system recognizes the fetal blood cells as 'foreign'." Id.

"Maternal alloantibodies against the Rh D antigen are known to result in brain damage in humans secondary to hemolytic disease of the fetus and newborn (HDN). . . . Post partum, HDN results in an accumulation of bilirubin in the neonate's circulation, which may result in kernicterus, a yellow staining of neuronal elements of the brain, including the basal ganglia and hippocampus. Infants who survive kernicterus often suffer from lasting brain damage." Id., page 6.

The specification discloses that a child whose blood cells display the Cw antigen have a predisposition to psychosis (e.g., schizophrenia) if the child's mother has anti-Cw antibodies in her blood circulation. See page 6: "The present invention describes a method to detect the predisposition of psychosis resulting from the presence of a rare HLA C allele, Cw antigen, in the progeny of a Cw negative mother, where the mother's immune system has produced an antibody against the progeny's Cw antigen."

Discussion

The claims are directed to methods (claims 1-9, 11, and 13) and kits claims (10 and 12) for detecting a predisposition to psychosis by detecting the presence of anti-Cw antibody. The examiner rejected all of the claims as nonenabled, on the basis that Appellant has not adequately shown that anti-Cw antibodies are indicative of an increased risk of psychosis. See the Examiner's Answer, page 3:

> [M]any dispositions, outside the realm of psychotic disorders may be determined by measuring these antibodies. For example, numerous studies, including Curtin et al., . . . disclose the measurement of these antibodies for the determination of hemolytic disease. Therefore, how can the determination of the same antibodies be used to determine psychosis with the exclusion of other disorders related to [C]w antibody presence?

The examiner also faulted the specification's working example:

> [T]here is insufficient guidance and working examples in the specification to enable one of skill in the art to determine predisposition to psychosis by measuring anti-[C]w antibodies. The one case study with only 1 subject referenced in the specification is grossly insufficient to meet this criterion of enablement. The results from one case study cannot possibly be used as a definitive statement that the method of applicant can be used in all cases and populations to determine predisposition to psychosis. Results of case studies must be readily reproducible, which has not been established in this instance.

Id., page 4.

"Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct." In re Armbruster, 512 F.2d 676, 678, 185 USPQ 152, 153 (CCPA 1975). Rather, "[w]hen rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of

protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

"[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

In this case, the examiner has not adequately shown that practicing the claimed method would have required undue experimentation. In fact, the examiner has not argued that the manipulative steps recited in the claims—obtaining a biological sample and testing it for the presence of anti-Cw antibody—would have required anything more than routine experimentation.

Instead, the examiner's concern seems to be that the specification does not definitively establish that the presence of anti-Cw antibody in a mother is in fact an indicator of increased risk of psychosis. However, the examiner has not pointed to any evidence or provided any reasoning to establish that anti-Cw antibody does not have the diagnostic meaning ascribed to it by the specification. In other words, the examiner has not provided "evidence or reasoning which is inconsistent with the contested statement." Marzocchi, 439 F.2d at 224, 169

USPQ at 370. Therefore, the initial burden of showing nonenablement has not been carried. The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

New Grounds of Rejection

1. Anticipation

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claims 1-7 and 9 are rejected under 35 U.S.C. § 102(b) as anticipated by Curtin. Curtin teaches a method comprising obtaining a sample from the mother of a child who possesses Cw blood antigen and determining the presence of anti-Cw antibody in the sample. See page 176, right-hand column: "Antibody identification studies were performed on Mrs. Q.W.'s serum and showed a strongly reactive anti-C^w. Further typing of the infant proved him to be C^w positive. . . . [T]his antibody reacted best using the indirect Coomb's test." Curtin teaches that the presence of anti-Cw antibodies was related to "mild hemolytic disease of the newborn" (abstract), not predisposition to psychosis. Nevertheless, we conclude that Curtin anticipates claims 1-7 and 9.

Claims 1 and 6 are independent claims directed to a method of diagnosing a predisposition to psychosis, comprising obtaining a biological sample from the mother of an infant with Cw blood antigen and testing it for the presence of anti-Cw antibody, where the presence of anti-Cw antibody is taken to indicate a predisposition to psychosis. Claims 2-5, 7, and 9 depend on claim 1 or claim 6.

The method claims in this case have three parts: a preamble ("A method for . . . comprising"), manipulative steps (obtaining a sample and determining the presence of anti-Cw antibody), and an interpretive "wherein" clause. The claims

thus raise the issue of what weight, if any, to give the preamble and "wherein" clause.

"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim. . . . If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

The preamble of claim 1 reads as follows: "A method for aiding in a diagnosis of a predisposition to psychosis in a progeny who possesses Cw blood antigen." The preamble of claim 6 reads simply "A method of screening for predisposition to psychosis."

The preamble of claim 1 is entitled to some weight, in that it helps to define the patient on whom the claimed process is performed. That is, the preamble of claim 1 states that the method is applicable to "a progeny who possesses Cw blood antigen," while the body of the claim states that the method is practiced using "a biological sample from the progeny's mother." Thus, the preamble of claim 1 limits the scope of the patients to whom the claimed process is applicable.

The remainder of claim 1's preamble and the entire preamble of claim 6 are not entitled to any weight because they do not constitute limitations of the claimed method. The phrases "aiding in a diagnosis of a predisposition to psychosis" and "screening for predisposition to psychosis" merely recite the purpose or intended use of the claimed methods. Therefore, the recitation of these phrases in the preambles of claims 1 and 6 do not constitute claim limitations and do not limit the claims.

Claims 1 and 6 also recite an interpretive "wherein" clause. Claim 1 states: "wherein the presence of an anti Cw antibody in the biological sample is indicative of a histocompatibility and a predisposition of the progeny to psychosis." Claim 6 states: "wherein the presence of an anti-Cw antibody is indicative of a predisposition to psychosis if donor's progeny possess Cw antigen."

We conclude that these recitations, as well, do not further limit the method defined by the claims. "A 'whereby' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim." Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed. Cir. 1993). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

In this case, the claims use the term "wherein", rather than "whereby", but we conclude that they should be treated the same. First, the process steps that are positively recited in the claims provide a result showing the presence or

absence of anti-Cw antibodies. The wherein clauses do not change anything about the recited steps but simply state a characterization of the results of those steps; i.e., in addition to showing, as previously known, a risk of hemolytic disease in the newborn, the presence of anti-Cw is interpreted also to indicate an increased risk of psychosis later in life. Cf. Minton, 336 F.3d at 1381, 67 USPQ2d at 1620-21 ("The term 'efficiently' [in the whereby clause] on its face does not inform the mechanics of how the trade is executed. . . . Rather, the term 'efficiently' is a laudatory one characterizing the result of the executing step."). Similarly here, the wherein clause does not inform the mechanics of how the "obtaining" and "determining" steps are performed; rather, the wherein clause merely characterizes the results of those steps. Therefore, the wherein clause is not entitled to weight in construing the claims.

Thus, we construe claim 1 to encompass a method comprising obtaining a biological sample from the mother of a progeny who possesses the Cw blood antigen, and determining the presence of anti-Cw antibody in the sample. We construe claim 6 to be directed to a method comprising obtaining a sample from a maternal donor and determining the presence of anti-Cw antibody in the sample. These claims thus read on the method taught by Curtin.

Claims 2-4 and 7 also read on Curtin. Claims 2-4 specify types of psychosis that the test indicates the progeny is predisposed to, and claim 7 adds a limitation to the conditions under which a positive result is interpreted to indicate a predisposition to psychosis. Thus, these additional limitations in these claims

add only to the intended use recited in the independent claims and therefore do not further limit claim 1 or claim 6.

Claim 5 adds the limitation to claim 1 that the mother and progeny have a compatible blood type. This limitation is met by Curtin, since the mother and infant in Curtin were both blood type A positive. See page 176, left-hand column.

Claim 9 adds the limitation to claim 6 that the donor is post-partum. This limitation is met by Curtin, since all the testing described therein was performed after the progeny was born. See page 176.

2. Obviousness

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claim 8 is rejected under 35 U.S.C. § 103(a) as obvious in view of Curtin.

As discussed above, Curtin teaches a method comprising obtaining a sample from a mother and determining the presence of anti-Cw antibody in the sample. See page 176, right-hand column. The mother tested in Curtin was post-partum, not pregnant as required by claim 8. However, Curtin expressly suggests that the method should be carried out on pregnant women. See the abstract: "A recommendation is made that maternal sera be tested against the father's cells at least once during each pregnancy." That is, Curtin suggests that the father's cells should be tested for the presence of Cw antigen and the mother's serum should be tested for the presence of anti-Cw antibodies "at least once during each pregnancy." Thus, Curtin suggests the method of instant claim 8.

3. Claim 10-13

We do not enter a new ground of rejection of claims 10-13. Claims 10 and 12 are directed to a "kit for use in diagnosis of psychosis" (presumably meaning predisposition to psychosis). The claimed kit comprises a sample containing anti-Cw antibody, a detector that binds anti-Cw antibody, and instructions for using the kit "to diagnose a predisposition to psychosis" or "according to the method of claim 1." Likewise, claim 13 is directed to a method comprising "utilizing a kit" such as that defined by claim 10 or claim 12.

Claim 11 defines a method that requires testing for anti-Cw antibody in a sample from the individual being tested, not (as in Curtin) testing for anti-Cw antibody in the individual's mother. Curtin does not appear to teach or suggest testing for anti-Cw antibody in a sample from an individual who is positive for Cw antigen.

We do not see all of the limitations of these claims disclosed or suggested by the prior art cited in the briefs or the Examiner's Answer. However, our decision not to enter new grounds of rejection does not necessarily mean we consider these claims allowable. The examiner is more familiar with this area of technology and may be aware of prior art that would be adequate to support a rejection of one or more of claims 10-13.

We note, for example, that earlier in prosecution a kit claim was rejected for obviousness. See Paper No. 5, mailed April 26, 2001. The claim was amended to add a limitation requiring "instructions for using the antibody and detector to diagnose a predisposition to psychosis" (Paper No. 6, filed July 30, 2001), and the

rejection was withdrawn (see Paper No. 7, mailed October 10, 2001, which does not repeat the rejection).

As we have construed it, however, the method defined by claim 1 is not further limited by its preamble or its "wherein" clause. It is therefore unclear whether the inclusion of an "instructions" limitation in the kit claims would distinguish those claims over the prior art. Thus, although we do not enter new grounds of rejection of claims 10-13, we encourage the examiner to consider the prior art in light of our interpretation of the claims, discussed above. If this application is subject to further prosecution, and the examiner believes that claims 10-13 should properly be rejected over the prior art, those claims should be rejected as well.

Summary

We reverse the examiner's rejection for nonenablement because the claims are entitled to an initial presumption of enablement and the examiner has not overcome that presumption. However, we enter new grounds of rejection based on anticipation and obviousness because the claimed method is indistinguishable from methods taught in or suggested by the prior art.

REVERSED, 37 CFR 1.196(b)

Toni R. Scheiner)
Administrative Patent Judge)
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Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Lora M. Green) INTERFERENCES
Administrative Patent Judge)

EG/dym

Hamilton, Brook, Smith & Reynolds, P.C.
530 Virginia Road
P.O. Box 9133
Concord, MA 01742-9133